



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

August 21, 2014

Dallen Medical, Inc.  
Mr. Al Memmolo  
Chief Operating Officer  
1046 Calle Recodo Suite G  
San Clemente, California 92673

Re: K141264  
Trade/Device Name: Tensyn™ Band  
Regulation Number: 21 CFR 888.3030  
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories  
Regulatory Class: Class II  
Product Code: HTN  
Dated: June 27, 2014  
Received: June 30, 2014

Dear Mr. Memmolo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Lori A. Wiggins -S**

for

Mark N. Melkerson

Director

Division of Orthopedic Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

**Indications for Use Statement**Page 1 of 1510(k) Number (if known): K141264Device Name: **Tensyn™ Band**

Indications for Use:

Tensyn™ Band is intended to provide fixation during the healing process following a syndesmotic trauma, such as fixation of syndesmosis (syndesmosis disruptions) in connection with Weber B and C ankle fractures which have been properly stabilized and which allow stable placement of the Tensyn™ Band apart from any other fixation hardware. For fixation during the healing process of acromioclavicular separations due to coracoclavicular ligament disruptions, the Tensyn™ Band is used in conjunction with, but not connected to, supplemental fixation.

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use \_\_\_\_\_

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



**This 510(k) summary information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.**

**GENERAL INFORMATION**

**APPLICANT:** Dallen Medical, Inc.  
1046 Calle Recodo, Suite G  
San Clemente, CA 92673  
(949) 218-0030 Phone  
(949) 218-0040 Fax

**CONTACT PERSON:** Al Memmolo  
Chief Operating Officer

**DATE PREPARED:** August 15, 2014

**DEVICE DESCRIPTION:**

**TRADE NAME:** Tensyn™ Band

**GENERIC/COMMONNAME** Button / Lock / Suture

**CLASSIFICATION NAME:** Washer, Bolt Nut, CFR 888.3030 (code HTN)

**DEVICE CLASSIFICATION:** Class II

**PREDICATE DEVICES:** Tenysn™ Band (K133858)  
OrthoHelix Syndesmosis Fixation Devices (K132733)

**Product Description:**

The Tensyn™ Band is a knotless system for fixation of syndesmosis disruptions and AC joint in the shoulder. The Tensyn™ Band is a low profile system comprised of a polymer coated flat polyethylene terephthalate (PET) suture band tensioned and secured between a narrow button and a lock. The Tensyn™ Band is available in titanium and stainless steel.

**Indications for Use:**

Tensyn™ Band is intended to provide fixation during the healing process following a syndesmotic trauma, such as fixation of syndesmosis (syndesmosis disruptions) in connection with Weber B and C ankle fractures which have been properly stabilized and which allow stable placement of the Tensyn™ Band apart from any other fixation hardware. For fixation during the healing process of acromioclavicular separations due to coracoclavicular ligament disruptions, the Tensyn™ Band is used in conjunction with, but not connected to, supplemental fixation.

**Technical Characteristics:**

The Tensyn™ Band has similar physical and technical characteristics to the predicate devices since all devices achieve fixation through a suture between two metal fasteners.

**Performance Data:**

All necessary testing has been performed with the Tensyn™ Band to assure substantial equivalence to the predicate devices. Testing included rotational loading, cyclic loading, ultimate load, load at 3 mm and shear test. The testing demonstrated that the Tensyn™ Band is substantially equivalent to the predicate devices.

**Basis for Determination of Substantial Equivalence:**

Upon reviewing the technical information provided in this submission and comparing intended use, principle of operation, performance data, and overall technological characteristics, the Tensyn™ Band is determined to be substantially equivalent to existing legally marketed devices.